CLAIMS

We claim:

1. A method of transdermally delivering testosterone to a male subject to treat hypogonadism, comprising: applying a hydroalcoholic gel to skin of the male subject, wherein the hydroalcoholic gel comprises testosterone in an amount effective to treat the hypogonadism.

2. The method of claim 1, wherein the application is for a period of at least 7 days.

3. The method of claim 1, wherein the period is at least 30 days.

4. The method of claim 1, wherein the period is at least 180 days.

5. The method of claim 1, wherein the application of the hydroalcoholic gel exhibits dose proportionality.

6. The method of claim 1, wherein the application results in a steady-state testosterone 24-hour pharmacokinetic profile in the male subject, having a small increase at about two hours after application followed by a decrease to a testosterone concentration that remains relatively constant for the remainder of the day.

7. The method of claim 6, wherein the application results in a steady-state testosterone 24-hour pharmacokinetic profile approximating the profile shown in FIG. 1(c).

8. The method of claim 6, wherein the relatively constant testosterone serum concentration is between about 300 ng/dL and about 1,000 ng/dL.

9. The method of claim 1, wherein the application causes an increased average dihydrotestosterone serum concentration in the male subject.

10. The method of claim 1, wherein the application causes an increase in the bone mineral density of the male subject.

11. The method of claim 10, wherein the increase in the bone mineral density occurs in the spine and/or hip.

12. The method of claim 1, wherein the application causes increased libido in the male subject.

13. The method of claim 1, wherein the application causes improved sexual performance in the male subject.

14. The method of claim 13, wherein the improved sexual performance comprises an increase in the percentage of full erection by the male subject.

15. The method of claim 1, wherein the application causes improved mood in the male subject.

16. The method of claim 1, wherein the application causes increased muscle strength in the male subject.

17. The method of claim 16, wherein the increased muscle strength occurs in the legs of the male subject.

18. The method of claim 1, wherein the application causes improved body composition in the male subject.

19. The method in claim 18, wherein the improved body composition comprises a decrease in the fat percentage of the male subject.

20. The method of claim 1, wherein the application causes negligible skin irritation.

21. The method of claim 1, wherein the testosterone C_{max} and C_{min} is within the normal range of an eugonadal male subject.

22. A method of transdermally delivering testosterone to a male subject to treat hypogonadism, comprising: applying a hydroalcoholic gel to skin of the male subject in an amount effective to treat the hypogonadism, wherein the hydroalcoholic gel comprises testosterone, and a penetration enhancer selected from the group consisting of isostearic acid, octanoic acid, lauryl alcohol, ethyl oleate, isopropyl myristate, butyl stearate, methyl laurate, diisopropyl adipate, glyceryl monolaurate, tetrahydrofurfuryl alcohol, polyethylene glycol ether, polyethylene glycol, propylene glycol, 2-(2-ethoxyethoxy) ethanol, diethylene glycol monomethyl ether, alkylaryl ethers of polyethylene oxide, polyethylene oxide monomethyl ethers, polyethylene oxide dimethyl ethers, dimethyl sulfoxide, glycerol, ethyl acetate, acetoacetic ester, N-alkylpyrrolidone, and terpene, and mixtures thereof.

23. The method of Claim 22, wherein the hydroalcoholic gel further comprises a C1-C4 alcohol comprising at least one of ethanol, 2-propanol, n-propanol, and mixtures thereof.

24. The method of Claim 22, wherein the testosterone is present in a concentration of about 0.1% to about 10% weight to weight of the hydroalcoholic gel.

25. The method of Claim 22, wherein the testosterone is present in a concentration of about 0.5% to about 5% weight to weight of the hydroalcoholic gel.

26. The method of Claim 22, wherein the testosterone is present in a concentration of about 1% weight to weight of the hydroalcoholic gel.

27. The method of Claim 22, wherein the testosterone comprises an enantiomer, a racemic mixture, a derivative, or a base or salt thereof.

28. The method of Claim 22, wherein the penetration enhancer is isopropyl myristate.

29. The method of Claim 28, wherein the isopropyl myristate is present in a concentration of about 0.1% to about 5% weight to weight of the hydroalcoholic gel.

30. The method of Claim 28, wherein the isopropyl myristate is present in a concentration of about 0.5% weight to weight of the hydroalcoholic gel.

31. The method of Claim 22, wherein the penetration enhancer is lauryl alcohol.

32. The method of Claim 22, wherein the hydroalcoholic gel further comprises polyacrylic acid.

33. The method of Claim 32, wherein the polyacrylic acid is present in a concentration of about 0.1% to about 5% weight to weight of the hydroalcoholic gel.

34. The method of Claim 22, wherein the hydroalcoholic gel further comprises sodium hydroxide.

35. A method of transdermally delivering testosterone to a male subject to treat hypogonadism, comprising: applying a hydroalcoholic gel to skin of the male subject in an amount effective to treat the hypogonadism, wherein the hydroalcoholic gel comprises testosterone, a C1-C4 alcohol, and a penetration enhancer selected from the group consisting of isopropyl myristate and lauryl alcohol.

36. The method of Claim 35, wherein the alcohol is ethanol.

37. The method of Claim 35, wherein the penetration enhancer is isopropyl myristate.

38. The method of Claim 35, wherein the penetration enhancer is lauryl alcohol.

39. The method of Claim 38, wherein the isopropyl myristate is present in a concentration of about 0.1% to about 5% weight to weight of the hydroalcoholic gel.

40. The method of Claim 35, wherein the isopropyl myristate is present in a concentration of about 0.5% weight to weight of the hydroalcoholic gel.

41. The method of Claim 35, wherein the lauryl alcohol is present in an amount of about 0.1% to about 3% weight to weight of the hydroalcoholic gel.

42. The method of Claim 35, wherein the hydroalcoholic gel further comprises polyacrylic acid.

43. The method of Claim 42, wherein the polyacrylic acid is present in a concentration of about 0.1% to about 5% weight to weight of the hydroalcoholic gel.

44. The method of Claim 35, wherein the testosterone is present in a concentration of about 0.1% to about 10% weight to weight of the hydroalcoholic gel.

45. The method of Claim 35, wherein the testosterone is present in a concentration of about 0.5% to about 5% weight to weight of the hydroalcoholic gel.

46. The method of Claim 35, wherein the testosterone is present in a concentration of about 1% weight to weight of the hydroalcoholic gel.

47. The method of Claim 35, wherein the testosterone comprises an enantiomer, a racemic mixture, a derivative, or a base or salt thereof.

48. A method of transdermally delivering testosterone to a male subject to treat hypogonadism, comprising: applying a hydroalcoholic gel to skin of the male subject in an

amount effective to treat the hypogonadism, wherein the hydroalcoholic gel comprises about 0.5% to about 5% testosterone, about 0.1% to about 2% polyacrylic acid, about 0.1% to about 2% isopropyl myristate, and about 40% to about 90% ethanol, wherein such percentages are weight to weight of the hydroalcoholic gel.

49. The method of Claim 48, wherein the testosterone is present in a concentration of about 1%, the ethanol is present in a concentration of about 72.5%, the isopropyl myristate is present in a concentration of about 0.5%, and the polyacrylic acid is present in a concentration of about 0.9% wherein such percentages are weight to weight of the hydroalcoholic gel.

50. The method of Claim 49, wherein the hydroalcoholic gel further comprising water.

51. The method of Claim 49, wherein the hydroalcoholic gel further comprises sodium hydroxide.

52. A method of transdermally delivering testosterone to a male subject to treat hypogonadism, comprising: applying a hydroalcoholic gel to skin of the male subject in an amount effective to treat the hypogonadism, wherein the hydroalcoholic gel comprises testosterone, a C1-C4 alcohol, and isopropyl myristate.

53. The method of Claim 52, wherein the gel weighs about 1.0 grams to 10.0 grams.

54. The method of Claim 52, wherein the gel weighs about 2.5 grams to about 7.5 grams.

55. The method of Claim 52, wherein the gel weighs about 2.5 grams to about 5.0 grams.

56. The method of Claim 52, wherein the testosterone is present in a concentration of about 0.1% to about 10% weight to weight of the hydroalcoholic gel.

57. The method of Claim 52, wherein the testosterone is present in a concentration of about 0.5% to about 5% weight to weight of the hydroalcoholic gel.

58. The method of Claim 52, wherein the testosterone is present in a concentration of about 1% weight to weight of the hydroalcoholic gel.

59. The method of Claim 52, wherein the testosterone comprises an enantiomer, a racemic mixture, a derivative, or a base or salt thereof.

60. The method of Claim 52, wherein the isopropyl myristate is present in a concentration of about 0.1% to about 5% weight to weight of the hydroalcoholic gel.

61. The method of Claim 52, wherein the isopropyl myristate is present in a concentration of about 0.5% weight to weight of the hydroalcoholic gel.

62. The method of Claim 52, wherein the hydroalcoholic gel further comprising polyacrylic acid.

63. The method of Claim 62, wherein the polyacrylic acid is present in a concentration of about 0.1% to about 5% weight to weight of the hydroalcoholic gel.

64. The method of Claim 52, wherein the alcohol is about 40% to about 90% ethanol weight to weight of the hydroalcoholic gel.

65. A method of transdermally delivering testosterone to a male subject to treat hypogonadism, comprising: applying a hydroalcoholic gel to skin of the male subject in an amount effective to treat the hypogonadism, wherein the hydroalcoholic gel is in a unit dose packet comprising a foil container having an inner surface and an outer surface, and a pharmaceutical composition inside the container, the composition comprising testosterone, a C1-C4 alcohol, and isopropyl myristate.

66. The method of Claim 65, wherein the composition weighs about 1.0 grams to about 10.0 grams.

67. The method of Claim 65, wherein the composition weighs about 2.5 grams to about 5.0 grams.

68. The method of Claim 65, wherein the composition is a hydroalcoholic gel.

69. The method of Claim 68, wherein the gel weighs about 2.5 grams to about 10.0 grams.

70. The method of Claim 65, wherein the testosterone is present in a concentration of about 0.1% to about 10% weight to weight of the composition.

71. The method of Claim 65, wherein the testosterone is present in a concentration of about 0.5% to about 5% weight to weight of the composition.

72. The method of Claim 65, wherein the testosterone is present in a concentration of about 1% weight to weight of the composition.

73. The method of Claim 65, wherein the testosterone comprises an enantiomer, a racemic mixture, a derivative, or a base or salt thereof.

74. The method of Claim 65, wherein the isopropyl myristate is present in a concentration of about 0.1% to about 5% weight to weight of the composition.

75. The method of Claim 65, wherein the isopropyl myristate is present in a concentration of about 0.5% to about 0.7% weight to weight of the composition.

76. The method of Claim 65, further comprising polyacrylic acid.

77. The method of Claim 76, wherein the polyacrylic acid is present in a concentration of about 0.1% to about 5% weight to weight of the composition.

78. The method of Claim 77, wherein the alcohol is about 40% to about 90% ethanol weight to weight of the composition.

79. The method of Claim 78, wherein the packet further comprises a polyethylene liner between the inner surface and the composition.